IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

		Attorney Docket No. 49931-0120
Applicant(s):	Edward W. MERRILL *et al.*	Confirmation No.: 3406
App. No.:	11/184,803	Examiner: S. Berman
Filing Date:	July 20, 2005	Group Art Unit: 1796
Title:	RADIATION AND MELT TREATED ULTRA HIGH MOLECULAR WEIGHT POLYETHYLENE PROSTHETIC DEVICES	

Commissioner for Patents
U.S. Patent and Trademark Office
PO Box 1450
Alexandria, Virginia 22331-1450

DECLARATION OF ORHUN K. MURATOGLU

I, Orhun K. Muratoglu, do hereby declare as follows:

1. I received my Ph.D. in Materials Science and Engineering, Program in Polymer Science and Technology, from the Massachusetts Institute of Technology ("MIT") in 1995. I have been engaged in the study of polymers, such as ultra high molecular weight polyethylene (UHMWPE), for use in medical implants for over 12 years. I have authored or co-authored at least 45 peer-reviewed articles and 14 book chapters and review articles concerning cross-linked and wear resistant UHMWPE and methods of making such UHMWPE for medical implants. I am currently the co-director of the Harris-Orthopedic Biomechanics and Biomaterials Laboratory at the Massachusetts General Hospital. A copy of my *curriculum vitae* is attached at tab 1.

2. I understand that the claims in the captioned patent application have been rejected under various grounds for written description, and anticipation/obviousness rejections in view of Salovey *et al.* (6,281,264), Shen *et al.* (6,228,900), Hyon *et al.* (6,168,626), Shalaby *et al.* (5,824,411), and Wiley (5,019,105). I am not an inventor of the subject matter claiming the captioned application.

3. The claimed product is obtainable by a process as recited in claim 124, which requires steps that include: (a) crosslinking, by irradiation, a preformed polymer in its solid state; (b) melting the crosslinked polymer; and (c) fashioning the implantable bearing component from the crosslinked and remelted polymer, wherein the polymer is selected from the group consisting of: ultra high molecular weight polyethylene, high-density-polyethylene, low-density-polyethylene, linear-low-density-polyethylene and polypropylene.

4. It is my understanding that applicants submitted a declaration (Rule 1.131 declaration, filed on July 16, 2004 in a related application US Serial No. 10/197,209, filed July 18, 2002, a copy of which is re-submitted herewith) showing the invention before the priority dates of the cited references (that is, prior to January 20, 1995), and that the process steps as recited in the claims are supported by the original specification. Apparently, the examiner could not determine whether the process steps inherently involves crosslinking by irradiation in steps with heating between the irradiations steps, and at the end of the process is clear to one skilled in the art in order to be able to say that the claims are enabling.

5. I have reviewed the Rule 1.131 declaration and found that Exhibit 3 of the declaration clearly shows the Experiment 2 described step by step process of irradiation, pause or cease in-between the passes, heating the consolidated polymer in-between the steps (that maintains a temperature above the room temperature), and continued irradiation until a total dose of up to 50 Mrads was attained (see below, as reproduced from the Exhibit 3):

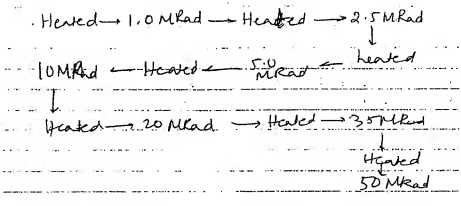
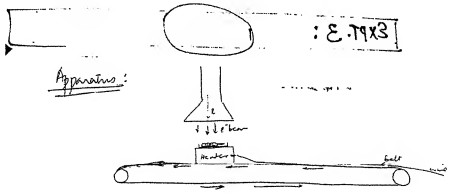


Exhibit 3 of the declaration also depicts a sketch of the van de Graaff generator as

the radiation source and a consolidated polymer on the conveyer belt passing under the radiation source (see below for the sketch as shown in Experiment 4, source: Exhibit 3 of the declaration):



This depiction shows the irradiation step using van de Graaff generator in the Experiment 4. The sample receives no radiation dose when it is outside of the e-beam radiation station and continues to move on the conveyer belt until it is put back on the belt for a second dose. The process is repeated to obtain a total dose of 5 Mrad or more, because the van de Graaff generator provides a dose of 2.5 Mrad per pass per pass in this experiment. The van de Graaff generator can also be adjusted to deliver higher or lower radiation doses per pass. It is therefore clear to the skilled persons and lay persons alike from the above sketch that there is a pause or the radiation ceases when sample passes out of the radiation zone and the steps of radiation and ceasing radiation are repeated with heating after each dose of radiation until the desired total dose is received by the sample.

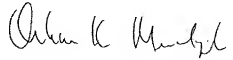
6. I also have reviewed the 08/600,744 patent application, as filed on February 13, 1996, which discloses a process for preparing a implantable bearing component by steps that include crosslinking, by irradiation, a preformed polymer in its solid state; and heating the crosslinked polymer after each dose of radiation until the desired total dose is received by the polymer. The process, as disclosed in Example 6 on pages 44-46 (of the 08/600,744 specification), shows that the polymeric material was above the room temperature throughout the irradiation process of cross-linking, including between two or after each dose of irradiation, that is, when the irradiation was ceased.

7. The instant specification also discloses that radiation doses are applied in sequential steps or passes, and subsequently the consolidated cross-linked polyethylene

is allowed to cool. Example 8 of the specification describes consolidated polyethylene (pucks) are treated with sequential steps or repeated passes of irradiation at a dose rate of 2.5 Mrad per pass to 2.5, 5, 7.5, 10, 12.5, 15, 17.5, 20, 30, and 50 Mrad total absorbed dose. That is, for a total absorbed dose of 5, 7.5, 10, 12.5, 15, 17.5, 20, 30, and 50, the radiation step is repeated for 2, 3, 4, 5, 6, 7, 8, 12, *etc.*, respectively. Clearly, the specification teaches sequential steps or passes (see Example 8 of the specification), heating and cooling after irradiation (see Examples 6 and 8 of the specification). Thus, it is obvious to one skilled in the art that the invention provides methods of repeated steps of irradiation, heating, and cooling of the cross-linked consolidated polyethylene. In other words, the instant specification discloses a method that inherently involves crosslinking by irradiation in steps with heating between the irradiations steps.

8. It is also clear from the specification that, for example, for a total dose of 5-20 Mrad at the dose rate of 2.5 Mrad per pass, it takes at least two passes of irradiation while the polyethylene is maintained at a temperature above the room temperature and the irradiation is ceased in between two or after each dose of irradiation (see for example, Example 9 at pages 48-49). In other words, heating the crosslinked polymer in-between the passes of irradiations and repeating of the steps were necessary at the time to complete the process in order to obtain a desired total dose of 5-20 Mrad at the dose rate of 2.5 Mrad per pass. Because, the van de Graaff generator used at the time generated a dose rate of 2.5 Mrad per pass (see specification, for example, page 33, 41, and 45). Thus, the original specification (as filed on February 13, 1996) teaches steps that inherently involves crosslinking by irradiation in steps with heating between the irradiations steps, as the person skilled in the art would immediately appreciate. Further, it is apparent from the Rule 1.131 declaration, that the steps shown under Experiment 2 and the sketch of the radiation using van de Graaff generator shown at Experiment 4 (see above) made the process clear to one skilled in the art. Therefore, the implantable bearing component prepared according to the methods disclosed in the original specification involved the steps of crosslinking, by irradiation, a preformed polymer in its solid state; heating of the crosslinked polymer; and fashioning the implantable bearing component from the crosslinked and remelted polymer.

9. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements and the like are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.



9/19/2008
Date

Orhun K. Muratoglu, Ph. D.

CURRICULUM VITAE

DATE PREPARED: July 16, 2008

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Place of Birth: Erzurum, Turkey

Education:

1991	B.S. (Materials Science and Engineering), Rensselaer Polytechnic Institute of Technology
1995	Ph.D. (Materials Science and Engineering, Program in Polymer Science and Technology), Massachusetts Institute of Technology

Academic Appointments:

1995-	Research Affiliate, Massachusetts Institute of Technology, Cambridge, MA
1995-2002	Instructor in Orthopedic Surgery, Harvard Medical – Orthopedic Surgery, Boston, MA
2002-2005	Assistant Professor of Orthopedic Surgery, Harvard Medical School – Orthopedic Surgery, Boston, MA
2005-	Associate Professor of Orthopedic Surgery, Harvard Medical School – Orthopaedic Surgery, Boston, MA

Hospital or Affiliated Institution Appointments:

1995-2002	Assistant Bioengineer, Orthopaedic Surgery, Massachusetts General Hospital, Boston, MA
1995-2002	Research Affiliate, Department of Chemical Engineering, Massachusetts Institute of Technology, Cambridge, MA
2001-2004	Deputy Director, Orthopedic Biomechanics and Biomaterials Laboratory, Massachusetts General Hospital, Boston, MA
2001-	Alan Gerry Scholar, Massachusetts General Hospital, Boston, MA
2004-	Co-Director, Orthopedic Biomechanics and Biomaterials Laboratory, Massachusetts General Hospital, Boston, MA

Professional Societies:

1990- Materials Research Society, Member
1990- American Chemical Society, Member
1995- American Institute of Chemical Engineers, Member
1995- Society for Biomaterials, Member
1996- American Society for Testing and Materials, Member
1997- Orthopaedic Research Society, Member
2000- American Academy of Orthopaedic Surgeons, Member
2003- American Academy of Hip and Knee Surgeons, Member

Editorial Boards:

1997- Ad-Hoc Reviewer, Clinical Orthopaedic and Related Research
1997- Ad-Hoc Reviewer, Journal of Biomedical Materials Research
1997- Ad-Hoc Reviewer, Biomaterials
2001 Ad-Hoc Reviewer, Austrian Science Fund
2003- Ad-Hoc Reviewer, Journal of Orthopaedic Research
2005- Ad-Hoc Reviewer, Polymer
2006- Ad-Hoc Reviewer, US-Israel Bi-national Science Foundation (BSF)

Awards and Honors:

1989-1990 Dean's List, Rensselaer Polytechnic Institute
1991 Summa cum Laude, Rensselaer Polytechnic Institute
1991 PPST Fellowship, Massachusetts Institute of Technology
1991 Matthew Albert Hunter Prize for Outstanding Academic Achievement, Rensselaer Polytechnic Institute
1992 Dupont Fellowship, Massachusetts Institute of Technology
1995 First Prize, Hoechst Celanese Polymer Poster Competition, Massachusetts Institute of Technology
1995 Summa cum Laude, Massachusetts Institute of Technology
1998 Best Paper Award, Montreal RETEC '97 Society of Plastics Engineers
1999 HAP Paul Award, International Society for Technology in Arthroplasty
2000 Partners in Excellence Award, Massachusetts General Hospital
2001 Marshall R. Urist Young Investigator Award, American Academy of Orthopaedic Surgeons
2006 HAP Paul Award, International Society for Technology in Arthroplasty

a. Invited Presentations

Invited Lectures

International Invited Lectures

2000 Invited Lecture: Highly crosslinked polyethylene in total joints at the 27th Annual Meeting, Japanese Hip Society, Nagoya, Japan
2000 Invited Lecture: European Knee Osteoarthritis Week, Arthroplasty Symposium, University of Ulm, Germany
2000 Invited Lecture: Irradiated and melted UHMWPE tibial knee inserts at the 85th National Congress, Torino, Italy, Italian Society of Orthopaedics and Traumatology

2000 Invited Lecture: Radiation crosslinked UHMWPE for total knees at the 2nd Harlaching Spring Symposium, Academic Hosp Munchen-Harlaching, Munich, Germany
2000 Invited Lecture: Residual free radicals in UHMWPE. Whistler 2000 Orthopaedic Symposium, Whistler, British Columbia, Zimmer
2001 Invited Lecture: Highly crosslinked polyethylenes in total joints at the Osteologie in Forschung und Praxis -Der Osteoblast, University of Wurzburg, Wurzburg, Germany
2001 Invited Lecturc: In vitro testing of highly crosslinked total knees at the Triennial Congress, Asian Pacific Orthopaedic Association, Adelaide, South Australia
2002 Invited Lecture: Radiation chemistry in improving wear and oxidation resistance of UHMWPE - 3rd Annual Turkish Arthoplasty Meeting, The Association of Turkish Arthroplasty Surgeons, Antalya, Turkey
2003 Invited Lecture: The effect of third body particles on in vivo wear of crosslinked acetabular liners at the Satellite Symposium, European Orthopaedic Research Society, Helsinki, Finland
2003 Invited Lecture: The state-of-the-art of crosslinked UHMWPEs in orthopedics at the Annual Meeting, European Federation of National Associations of Orthopaedic and Traumatology, Helsinki, Finland
2004 Invited Lecture: Limitations of contcmporary crosslinked polyethylenes and potential 2nd generation solutions, Peter Herberts Festchrift, Sahlgrenska University Hospital, Goteborg, Sweden
2004 Invited Lecture: Materials Science in Orthopaedics: Low-Wear, High Fatigue Polyethylenes for Total Joints, Biomcd Meeting, Ankara, Turkey
2005 Invited Lecture: The effect of alpha-tocopherol on the wear of radiation crosslinked UHMWPE, Oxidative Stabilization of UHMWPE, Turin, Italy
2005 Invited Lecture: Alpha-tocopherol stabilized irradiated accetabular liners, UHMWPE for arthroplasty: degradation, stabilization and crosslinking, Turin, Italy
2005 Invitcd Lecturc: Second Gencration Highly Crosslinked UHMWPE for Total Joint Arthroplasty, SICOT, Istanbul, Turkey
2006 Invited Lecture: Radiation Chemistry of Polyethylenes for Total Joint Application, IRaP, Antalya, Turkey
2006 Invited Lecturc: Presidential Gucst Lecturer: New Horizons in Polyethylcne Technology, European Hip Society, Antalya, Turkey

National Invited Lectures

1995 Invited Lecture: The effects of gamma sterilization on UHMWPE. Workshop on Polyethylene, Combined Orthopacdic Research Society
1998 Invited Lecture: The effect of crosslinking on wear at the Material Science and Engineering Colloquium Series, Ohio State University
1999 Invited Lecture: Seminar Series at the Mechanical Engineering, Aeronautical Engineering and Mechanics, Rensselaer Polytechnic Institute
1999 Invited Lecture: Hip simulator wear studies at the Hip, Knee, and Shoulder Symposium, University of Florida

2000 Invited Lecture: High cycle wear testing of highly crosslinked UHMWPE acetabular liners at the Hip, Knee, and Shoulder Symposium, University of Florida

2000 Invited Lecture: Wear 2000 Workshop, Orthopaedic Research Society

2000 Invited Lecture: Low wear and low oxidation with irradiated and melted UHMWPE at the Wear 2000 Workshop, American Academy of Orthopaedic Surgeons and National Institute of Health

2001 Invited Lecture: Workshop on Ultra-high molecular weight polyethylene , Society for Biomaterials

2001 Invited Lecture: New Test Methods for Evaluating the Performance of Conventional and Crosslinked UHMWPE , American Society for Testing and Materials

2001 Invited Lecture: Analysis of explanted highly crosslinked UHMWPE at the Tribology Issues in Biology and Medicine, Argonne National Laboratory

2002 Invited Lecture: Overview of radiation chemistry of UHMWPE for orthopedics at the Grand Rounds, University of Oklahoma College of Medicine

2002 Invited Lecture: Surface Analysis of Early Retrieved Acetabular Polyethylene Liners, American Society for Testing and Materials

2002 Invited Lecture: Overview of radiation chemistry of UHMWPE for orthopedics at the Grand Rounds, University of Utah

2002 Invited Lecture: Highly crosslinked polyethylenes in total hip and total knee at the Hip, Knee, and Shoulder Symposium, University of Florida

2002 Invited Lecture: Effect of Crosslinking on the Delamination and Adhesive Wear Behavior of Tibial Knee Inserts, The Knee Society Meeting, American Academy of Hip and Knee Surgeons

2003 Invited Lecture: Update on highly crosslinked polyethylenes in total hip and total knee at the Hip, Knee, and Shoulder Symposium, University of Florida

2003 Invited Lecture: E-beam crosslinked and melted polyethylene, Alternate bearing surfaces in total joint replacement, University of Pennsylvania Medical Center

2003 Invited Lecture: Highly crosslinked polyethylene in total knees: Another view, Alternate Bearing Surfaces in Total Joint Replacement, University of Pennsylvania Medical Center

2003 Invited Lecture: Highly crosslinked polyethylene in total knees: Another view, Alternate bearing surfaces in total joint replacement , University of Pennsylvania Medical Center

2003 Invited Lecture: E-beam crosslinked and melted polyethylene, Alternate bearing surfaces in total joint replacement, University of Pennsylvania Medical Center

2004 Invited Lecture: Update on highly crosslinked polyethylenes in total hip and total knee at the Hip, Knee, and Shoulder Symposium, University of Florida

2004 Invited Lecture: Radiation crosslinked and melting of polyethylene, Hip, Knee and Shoulder Symposium, University of Pennsylvania Medical Center

2004 Invited Lecture: Diminished Polyethylene wear using a highly crosslinked polyethylene, The Knee Society Meeting, American Academy of Hip and Knee Surgeons

2005 Invited Lecture: Vitamin E Stabilized, Irradiated UHMWPE for TKR, Advances in Hip and Knee Arthroplasty Meeting, Washington DC

2005 Keynote Presentation: Improving the Wear Resistance of Ultra-high Molecular Weight Polycthylene (UHWMPE), World Tribology Congress, Washington DC
2005 Invited Panel Discussion: Alternate Bearing Surfaces, 20th Annual Vail Orthopaedic Symposium, Vail, Colorado
2006 Invited Lecture: Crosslinked UHMWPE in Total Knees, ISTA Meeting, New York, NY
2007 Grand Rounds at Dartmouth: Second Generation Highly Crosslinked UHMWPEs, Hanover NH

Regional Invited Lectures
2002 Invited Lecture: Crosslinked polyethylenes at the Fall Meeting, New England Orthopaedic Society
2004 Invited Lecture: Second Gcneration Crosslinkcd Polyethylenes for Total Joints at the Traveling Fellow Program AOA Presentation, Massachusetts General Hospital
2004 Invited Lecture: Current and Future Crosslinked Polyethylenes, How Good are They?, American Orthopaedic Association
2005 Keynote Speaker: Crosslinked polyethylenes, Harvard Hip Course, Harvard Medical School
2006 Invited Lecture: Polyethylene: New Perspectives at the Traveling Fellow Program AOA Presentation, Massachusetts General Hospital
2006 Invited Lecture: Second Generation Polyethylene, Harvard Hip Course, Harvard Mcdical School.
2006 Invited Presentation: Cross-Linked Polyethylene for the Knee, Harvard Hip Course, Harvard Medical School.

Plenary Presentation
1998 Plenary Presentation: Effect of Crosslinking on Wcar of Polyethylene, Gordon Conference on Tribology

Bibliography

Original Articles

1. Muratoglu OK, Cohen RE, Argon AS, Weinberg M. Toughening mechanism of rubber modified polyamides. Polymer. 1995; 36(5):921.
2. Muratoglu OK, Cohen RE, Argon AS, Weinberg M. Microstructural Fracture Processes Accompanying Growing Cracks in Tough Rubber-Modified Polyamides. Polymer. 1995; 36(25):4787.
3. Muratoglu OK, Cohen RE, Argon AS, Weinberg M. Microstructural processes of fracture of rubber modified polyamides. Polymer. 1995; 36(25):4771.
4. Muratoglu OK, Cohen RE, Argon AS. Crystalline morphology of polyamide 6 near planar surfaces. Polymer. 1995; 36(11):2143.
5. Muratoglu OK, Jasty M, Harris WH. A new method to determine the locus of radiation damage in retrieved UHMWPE components. ASTM-SMP. 1997; (1307):79.

6. Muratoglu OK, Bragdon CR, O'Connor DO, Jasty M, Harris WH, Gul R, McGarry F. Unified wear model for highly crosslinked ultra-high molecular weight polyethylenes (UHMWPE). Biomaterials. 1999;20(16):1463-70.
7. Muratoglu OK, Bragdon CR, O'Connor DO, Jasty M, Harris WH. A novel method of cross-linking ultra-high-molecular-weight polyethylene to improve wear, reduce oxidation, and retain mechanical properties. Recipient of the 1999 HAP Paul Award. J Arthroplasty. 2001;16(2):149-60.
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12. Muratoglu OK, Bragdon CR, O'Connor D, Perinchief RS, Estok DM, Jasty M, Harris WH. Larger diameter femoral heads used in conjunction with a highly cross-linked ultra-high molecular weight polyethylene: a new concept. J Arthroplasty. 2001; 16(8 Suppl 1):24-30.
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35. Oral E, Wannomae K, Rowell S, Muratoglu OK. Migration Stability of α-tocopherol in Irradiated UHMWPE. Biomaterials. 2006; 27(11): 2434-2439.
36. Oral E, Christensen S, Wannomae KK, Malhi A, Muratoglu OK. Wear Resistance and Mechanical Properties of Highly Crosslinked UHMWPE Doped with Vitamin E. J Arthroplasty, 2006; 21(4): 580-591.
37. Wannomae KK, Bhattacharyya S, Freiberg AA, Estok D, Harris WH, Muratoglu OK. In vivo oxidation of retrieved crosslinked UHMWPE acetabular components with residual free radicals. Journal of Arthroplasty. 2006; 21(7): 1005-1011.
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39. Estok D, Burroughs B, Muratoglu OK, Harris WH. Comparison of Hip Simulator Wear of Two Different Highly Crosslinkcd UHMWPE Acetabular Components using both 32 and 38-mm Femoral Heads. Journal of Arthroplasty; in print.
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43. Muratoglu OK, Rubash HE, Bragdon CR, Burroughs BR, Huang A, Harris WH. Simulated Normal Gait Wear Testing of Highly Cross-Linked Polyethylene Tibial Inserts. Journal of Arthroplasty, 2007; 22 (3): 435-444
44. Oral E, Muratoglu OK. Vitamin C Hinders Radiation Cross-linking in Aqueous Poly (Vinyl Alcohol) Solutions. Nuclear Inst. and Methods in Physics Research. 2007; **B-265**: 92-97.
45. Oral E, Muratoglu OK. Radiation Cross-linking in Ultra-high Molecular Weight Polyethylene for Orthopaedic Applications. Nuclear Inst. and Methods in Physics Research. 2007; **B-265**: 18-22.
46. Bodugoz-Senturk H, Choi J, Oral E, Kung JH, Macias CE, Braithwaite G, Muratoglu OK. The effect of polyethylene glycol on the stability of pores in polyvinyl alcohol hydrogels during annealing, Biomaterials, 2008, 29(2):141-9.

Proceedings of Meetings

1. Argon AS, Bartczak Z, Cohen RE, Muratoglu OK. Novel mechanisms of toughening semi-crystalline polymers. In: Proc. 18th Riso International Symposium on Materials Science: Polymeric Composites-Expanding the Limits, Eds: Andersen SI, Brondted P, Lillhot H, Lystrup A, Rheinlander JT, Sorensen BF, Toftegaard H; 1997; Roskilde, Denmark; 1997.

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